Remarks

Claims 1 and 20 are amended to explicitly state features that were previously implicit in the claims. Applicants do not intend to narrow the scope of the claims by making these amendments, nor do they believe that the amendments narrow the claims.

Claim Rejections

35 U.S.C. § 102

Claims 1, 2, 4-10, and 18-24 were rejected as being anticipated by Lipari (U.S. Patent No. 4,383,992). Lipari teaches the use of a 0.12% prednisolone acetate solution. However, Lipari does not teach *topical* administration of a drug to treat or prevent a condition or disease affecting the vitreous humor and/or structures posterior to the vitreous humor or to deliver a therapeutically effective amount of the drug to the vitreous and/or posterior structures. Furthermore, the concentration of prednisolone acetate disclosed in the reference is lower than the effective concentration for delivery of a therapeutically effective amount of prednisolone to the vitreous humor and posterior structures where the concentration is administered topically. Thus, Lipari does not anticipate the claims.

35 U.S.C. § 103

Claims 3, 11, 12, 14, 16, 17 and 25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lipari (U.S. Patent 4,383,992) and Loftsson (U.S. Patent 4,572,954). A prima facie case of obviousness requires that the combined reference teach or suggest all of the claim features (see MPEP 2143). The cited references do not suggest that cyclodextrin compositions can be used to deliver a drug to the back of the eye (i.e. the vitreous humor and anything posterior thereto) via topical administration.

Eye drop compositions are generally used to treat diseases affecting the front of the eye, such as for reducing intraocular pressure in glaucoma, or for treatment of conjunctival or ocular surface infections or allergies and the like. Thus, the compositions of the cited references are not formulated with a sufficient concentration of the drug to provide a therapeutically effective amount of the drug to the back of the eye, and there is no suggestion to alter the compositions so they would be suitable for such use. Therefore, no prima facie case of obviousness has been established.

Finally, the Office Action has alleged that Applicants have presented no evidence to establish the unexpected or unobvious nature of the claimed compositions and methods. However, Applicants point out that Figures 2-4 and Example 2, beginning on p. 21 do provide such evidence. In particular, Applicants refer to Figure 4 and Table 2, which succinctly highlight the advantages of the present composition and method. As shown in Table 2, compositions 2a-2f all contain a cyclodextrin, while 2g does not. There is a significant barrier between the aqueous humor (AH) and vitreous humor (VH). For example, formulation 2g, which contains no cyclodextrin, provides a significant concentration of prednisolone to the aqueous humor, but is unable to deliver prednisolone from the aqueous humor to the vitreous humor. By contrast, all of the formulations with a cyclodextrin were able to deliver a significant amount of prednisolone through the barrier. Each of compositions 2a-2g was administered topically. Thus, the cyclodextrin has the unexpected and previously unknown property of being able to deliver a drug from

the aqueous humor to the vitreous humor and facilitating delivery to the back of the eye via topical administration.

This is a significant contribution to the art because at the time the application was filed, topical administration was generally ineffective, and delivery of drugs to the back of the eye was generally accomplished by injection into the eye or implantation of a drug delivery device. Thus, the present compositions and methods avoid the undesirable and unpleasant necessity of cutting or inserting sharp objects into the eye.

In light of the amendments and the arguments made herein. Applicants believe that the claims are patentable as they now stand, and respectfully request that Examiner remove the rejections and allow the application to pass to issue.

Please use Deposit Account 01-0885 for extension of time fees or any other fees or credits relating to this response.

Respectfully submitted,

Brent A. Johnson
Registration No. 51,851
Agent of Record

Please send all inquiries and correspondence to:

Brent A. Johnson
Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92612
Telephone: 714/246-4348
Telecopier: 714/246-4249

CERTIFICATE OF FIRST CLASS MAIL UNDER 37 C.F.R. §1.10

I hereby certify that this Response to the Office Action are being deposited with the United States Postal Service on **July 5, 2005**in an envelope as "First Class Mail Post Office To Addressee" with sufficient postage for First Class Mail addressed to Mail Stop: Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Bonnie Ferguson
Name of person mailing paper

Date: July 5, 2005

Signature of person mailing paper